UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,519	12/31/2003	Charles Richard Le Roy II		9243

7590 04/05/2007

Charles R. Le Roy II
P.O. Box 765
Stanfield, AZ 85272

EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,519	LE ROY ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-2 are pending.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim 1 is rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to

present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

It is unclear what the intended limitation of "Trolamine Salicylate-aspirin" is. It is noted that Trolamine salicylate is a single compound, however the examiner is not aware of the compound, Trolamine Salicylate-aspirin. Is applicant attempting to claim a mixture of trolamine-salicylate and aspirin (acetylsalicylic acid)? Further clarification is requested. Further, the examiner notes that applicant recites "tea tree oil-melaleuca". Tea tree oil is normally extracted from *Melaleuca alternifolia.* However, it is unclear what the inclusion of the botanical name is intended to convey and adds confusion to the claim. The examiner suggests the removal of the botanical name. This discussion pertains to Oil of Wintergreen-Gaultheris procumbens. Further, it is unclear what "Pearl Blue" is intended to limit the claim to. The examiner notes that this may be the name of applicant's commercialized product and since it does not impart any structural limitation, the examiner suggests removing this phrase.

Lastly, it is unclear if applicant is attempting to claim a combination of lidocaine HCL and Trolamine Salicylate-aspirin since it is narrative form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al (5,558,914) in view of Van Englen et al (6,416,772) in further view of Reader's Digest (The Healing Power of Vitamins, Minerals, and Herbs, 1999page 258-259).

Cohen et al teach a water-based formulation for treatment of sunburn. The composition comprises the critical ingredients of tea tree oil, spearmint oil, lidocaine HCl, and a component to reduce tack. See abstract. Specifically the composition may further contain mentholated product and other numbing products. See column 4, lines 29-31. Cohen teaches tea tree oil is further mixed with oils such as spearmint oil, wintergreen, oil, or peppermint oil. See column 5, lines 60-65.

Cohen does not teach the use of triethanolamine salicylate, almond oil, or aloe vera.

Van Engelen et al teach a topical dermal anesthetic for the relief of pain such as burns. See column 1, lines 5-10. The composition comprises an analgesic such as and preferably triethanolamine salicylate in a carrier including aloe vera.

Reader's Digest teaches the combination of chamomile and almond oil to treat sun burned areas. See page 258-259.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Cohen et al, Ven Engelen et al, and the teachings of Reader's Digest and utilize a combination of the instant components. One would have been motivated to do so with the expectation of an additive effect to treat pain associated with sunburn. For instance, Cohen suggests the use of other numbing agents and Van Engelen teaches triethanolamine salicylate is a preferable analgesic to help alleviate pain and Readers' Digest teaches almond oil helps treat sun burned areas. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 11310529 (partial computer translation) in view of Reed et al (6,299,900).

JP '529 teaches a local anesthetic comprising lidocaine or its salt and salicylic acid or its salt. See abstract. The salt of lidocaine many be selected from a hydrochloride, carbonate, and sulfate wherein the hydrochloride form is the most preferred. See [0006].

JP '529 does not teach triethanolamine salicylate.

Reed while teaching a transdermal composition, teaches non-steroidal anti0inflmmatory agents include salicylic acid, salicylamide, triethanolamine salicylate, etc. see column 6, lines 33-36.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of JP '529 and Reed et al and substitute JP's salicylic acid

with the instantly claimed triethanolamine salicylate. One would have been motivated to do so with a reasonable expectation of success and similar results since JP' 529 suggests the use of salicylic acid salts and Reed teaches that both salicylic acid and triethanolamine salicylate are anti-inflammatory agents. Therefore, it would have been prima facie obvious for a skilled artisan to substitute the prior art's salicylic acid with another salicylic acid derivative such as triethanolamine salicylate since the prior art establishes that both have the same function as and NSAID.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al (6,284,797) in view of Cohen et al (5,558,914) in view of Schutt et al (4,248,861) in further view of Allen (4,895,727).

Rhodes teaches a topical for the treatment of pain and to promote wound healing. See abstract. Rhodes teaches a sunburn cream comprising lidocaine, methyl salicylate, and vitamin E. Rhodes teaches the use of vitamin E or menthol or as the promoter of subcutaneous absorption. See claim 6. Rhodes teaches the use of various salicylate derivatives. Note column 3, lines 15-20.

Rhodes does not teach the inclusion of tea tree oil, aloe vera, wintergreen oil, and almond oil or specify the use of triethanolamine salicylate.

Cohen et al teach a water-based formulation for treatment of sunburn. The composition comprises the critical ingredients of tea tree oil, spearmint oil, lidocaine HCl, and a component to reduce tack. See abstract. Specifically the composition may further contain mentholated product and other numbing products. See column 4, lines 29-31. Cohen teaches tea tree oil is further

mixed with oils such as spearmint oil, wintergreen, oil, or peppermint oil. See column 5, lines 60-65.

Schutt et al teach a topical composition for treating sunburn comprising an unsaturated oil of almond, walnut, safflower, soybean, or peanut oil or alternatively a mixture of almond, walnut, safflower, soybean, and peanut oil. Schutt teaches this oil provides improved and rapid healing of sunburn. See column 4, lines 60-67. Aloe provides increased therapeutic effects (column 3, lines 25-31) and methyl salicylate provides a highly desirable effect as a counterirritant (column 3, lines 40-45). A preferred composition contains aloe vera gel , methyl salicylate, and the unsaturated oils.

Allen while teaching a topical composition with enhanced penetration, teaches analgesics suitable for treating pain and itching, inflamed skin, sunburn, burns, wounds, etc. include salicylic acid derivatives, trolamine salicylate, methyl salicylate; antipyrine, aspirin, and salicylamide. See column 5, line 65 to column 5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Rhodes, Cohen et al, Schutt et al, and Allen and utilize the instant components in a combination to treat sunburn. One would have been motivated to do so with a reasonable expectation of success and similar results since Cohen et al who teaches a composition comprising lidocaine HCl, tea tree oil, and a fragrance oil selected from either wintergreen oil or spearmint oil is effective to treat sunburn. Further, Schutt teaches oils such as almond oil are effective in treating sunburn and aloe increases the therapeutic effect. Therefore, it would have been obvious to combine the ingredients for an additive effect. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the

same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute methyl salicylate with the instant triethanolamine salicylate. One would have been motivated to do so with a reasonable expectation of success and similar results since Rhodes teaches the use of various salicylic acid derivatives and Allen teaches both methyl salicylate and triethanolamine salicylate are analgesic that treat sunburn. Therefore, it would have been prima facie obvious for a skilled artisan to substitute the prior art's salicylic methyl salicylate with another salicylic acid derivative such as triethanolamine salicylate since the prior art establishes that both have the same function as an analgesic for treating sunburn.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al (6,284,797) in view of Allen (4,895,727).

Rhodes teaches a topical for the treatment of pain and to promote wound healing. See abstract. Rhodes teaches a sunburn cream comprising lidocaine, methyl salicylate, and vitamin E. Rhodes teaches the use of vitamin E or menthol or as the promoter of subcutaneous absorption. See claim 6. Rhodes teaches the use of various salicylate derivatives. Note column 3, lines 15-20.

Rhodes does not teach specify triethanolamine salicylate.

Allen while teaching a topical composition with enhanced penetration, teaches analgesics suitable for treating pain and itching, inflamed skin, sunburn, burns, wounds, etc. include

salicylic acid derivatives, trolamine salicylate, methyl salicylate; antipyrine, aspirin, and salicylamide. See column 5, line 65 to column 5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute methyl salicylate with the instant triethanolamine salicylate. One would have been motivated to do so with a reasonable expectation of success and similar results since Rhodes teaches the use of various salicylic acid derivatives and Allen teaches both methyl salicylate and triethanolamine salicylate are analgesic that treat sunburn. Therefore, it would have been prima facie obvious for a skilled artisan to substitute the prior art's salicylic methyl salicylate with another salicylic acid derivative such as triethanolamine salicylate since the prior art establishes that both have the same function as an analgesic for treating sunburn. With regard to the salt derivate of lidocaine, this would have been obvious to those skilled in the art since lidocaine is conventionally utilized in the hydrochloride salt form.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharmila S. Gollamudi
Primary Examiner
Art Unit 1616

SSG